PATENT
Docket No. 406462000200

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

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Nora Durant

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

George H. Lowell et al.

Serial No.: 09/214,701

Filing Date: September 30, 1999

For: PROTEIN AND PEPRIDE VACCINES FOR INDUCING MUCOSAL IMMUNITY

Examiner: J. Parkin

Group Art Unit: 1614

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

The documents listed on the attached Form PTO-1449 were cited in a Search Report (copy attached) directed to a counterpart international or foreign application.

This Information Disclosure Statement is submitted:

- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☒ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of * is enclosed.
  - ☒ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowauce, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of * is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 406462000200. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 21, 2001

Respectfully submitted,

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PTO/SB/08 (2-92)
Sheet 1 of 1

Form PTO-1449	Docket Number 406462000200	Application Number 09/214,701
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant: George H. Lowell et al.	
(Use several sheets if necessary)	Filing Date September 30, 1999	Group Art Unit 1614
	Mailing Date: December 21, 2001	

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO

OTHER DOCUMENTS *(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
	1.	Levi et al. (1995) Vaccine 13(4):1353-1359
	2.	Lowell et al. (1988) *J Exp Med* 167:658-663
	3.	Lowell et al. (1988) *Science* 240:800-802

EXAMINER:	DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US97/12253

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(6): A61K 38/00; C07K 1/00; A61K 39/21, 39/385, 45/00 and US CL: 530/300, 402, 403; 424/188.1, 193.1, 278.1, 283.1

V. 1. REASONED STATEMENTS:
The report as to Novelty was positive (YES) with respect to claims 6, 10, 15, 16, 18, 23, 26, and 29-32.
The report as to Novelty was negative (NO) with respect to claims 1-7, 11-14, 17, 19-22, 25, 27, and 28.
The report as to Inventive Step was positive (YES) with respect to claims NONE.
The report as to Inventive Step was negative (NO) with respect to claims 1-8, 10-23, and 25-32.
The report as to Industrial Applicability was positive (YES) with respect to claims 1-8, 10-23, and 25-32.
The report as to Industrial Applicability was negative (NO) with respect to claims NONE.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
vaccine compositions comprising an antigen with endogenous hydrophobic sequence of between about 3 and about 50 amino acids coupled to an exogenous hydrophobic sequence, which in turn is complexed with a proteosomes to form a proteosomal composition (refer to page 659, first paragraph and Materials and Methods). This teaching also discloses the coupling of lauroyl or pentapeptide (Phe-Leu-Leu-Ala-Val) groups to the antigen of interest to facilitate proteosomal complex formation. Proteosomal complexes were formed in the presence of detergent which was subsequently removed through dialysis. This teaching does not specifically describe vaccine compositions comprising HIV gp160 antigens or the administration of said vaccine compositions via intranasal or respiratory routes.

Lowell *et al.* (1988b) teaches the preparation of vaccine compositions comprising an antigen with endogenous hydrophobic sequence of between about 3 and about 50 amino acids coupled to an exogenous hydrophobic sequence, which in turn is complexed with a proteosomes to form a proteosomal composition (refer to page 659, first paragraph and Materials and Methods). This teaching also discloses the coupling of lauroyl or pentapeptide (Phe-Leu-Leu-Ala-Val) groups to the antigen of interest to facilitate proteosomal complex formation. Proteosomal complexes were formed in the presence of detergent which was subsequently removed through dialysis. Cysteine residues were also added between the antigen and hydrophobic foot to enhance the immunogenic properties of the vaccine composition. This teaching also fails to disclose vaccine compositions comprising HIV gp160 antigens or the administration of said vaccine compositions via intranasal or respiratory routes.

VanCott *et al.* (1995) teaches that oligomeric HIV gp160 displays high reactivity toward divergent mAbs and should be included in potential HIV vaccines (see page 103, Abstract and page 115, Discussion). Levi *et al.* (1995) teaches that the intranasal immunization of mammals with proteosomal vaccines confers protection following viral challenge. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to utilize known immunogens derived from infectious agents, as taught by VanCott *et al.* (1995) and Levi *et al.* (1995), in the proteosomal compositions described by Lowell *et al.* (1988a, 1988b), since this represents an efficient means for generating antigen-specific immune responses. One of ordinary skill in the art would be motivated to utilize different immunization sites (e.g., intranasal) and regimens depending upon the nature of the immune response desired (e.g., mucosal). Finally, one of ordinary skill in the art could employ lyophilization, or other art-recognized methods of vaccine preparation, to make the proteosomal compositions.

NEW CITATIONS

LOWELL et al. Peptides Bound to Proteosomes via Hydrophobic Feet Become Highly Immunogenic Without Adjuvants. J. Exp. Med. February 1988, Vol. 167, pages 658-663, see entire document.

LOWELL et al. Proteosome-Lipopeptide Vaccines: Enhancement of Immunogenicity for Malaria CS Peptides. Science. 06 May 1988, Vol. 240, pages 800-802, see entire document.

VANCOTT et al. Characterization of a Soluble, Oligomeric HIV-1 gp160 Protein as a Potential Immunogen. J. Immunol. Methods. 1995, Vol. 183, pages 103-117, see entire document.

LEVI et al. Intranasal Immunization of Mice Against Influenza with Synthetic Peptides Anchored to Proteosomes. Vaccine. 1995, Vol. 13, No. 14, pages 1353-1359, see entire document.